

REMARKS/ARGUMENTS

The Status of the Claims.

Claims 5-30 and 58 are pending with entry of this amendment, claims 1-4 being cancelled herein. Cancellation of these claims is without prejudice, without intent to abandon any originally-claimed subject matter, and without intent to acquiesce in any rejection of record. Applicants expressly reserve the right to file one or more continuing applications containing these cancelled claims.

Claims 5, 7-15, 21, 22, and 28 are amended herein. These amendments are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter or agreement with any objection or rejection of record. No new matter has been added to the application by way of the above amendments, which are entirely formal in nature. Accordingly, entry of the Amendment is respectfully requested.

The Information Disclosure Statement.

Applicants note with appreciation the Examiner's thorough consideration of the references cited in the Information Disclosure Statement (Form 1449) submitted on June 17, 2003.

35 U.S.C. §112, Second Paragraph.

Claim 10 was rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite with respect to the term "gamma-b." Claims 13, 14, and 17-20 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite with respect to the term "beta-b." Applicants traverse to the extent that the rejection applies to the claims as amended.

Claims 10, 13, 14, and 17-20 as amended are dependent from amended claim 5, in which the encoded fusion protein includes "a viral protein obtained from a plant single-stranded RNA virus, wherein the plant single-stranded RNA virus is a hordeivirus." While Applicants do not concur that the claim language is indefinite, in order to facilitate prosecution, Applicants have amended claims 10 and 13 claims to further clarify the source of the viral protein as helpfully suggested by the Examiner. Applicants submit that one of skill in the art related to hordeiviruses would readily understand what these viral proteins are and from where they are derived. For example, one of skill in the art would have readily been aware of Petty et al "Identification of barley stripe mosaic virus genes involved in viral RNA replication and systemic movement" (IDS reference 72, published in 1990) and Donald and Jackson "RNA-binding activities of barley stripe mosaic virus gamma-b fusion proteins" (IDS reference 34, published in 1996). Applicants submit that the amended claims are not indefinite and respectfully request that the rejection be withdrawn.

35 U.S.C. §112, First Paragraph.

Claims 1-6, 8-30 and 58 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter not described in the specification. Applicants traverse.

The Action alleges that the specification does not provide a structural description of what comprises an autoproteolytic peptide or a functional requirement or description. While the Examiner has helpfully suggested that Applicants further limit the claims to 2A autocatalytic peptides derived from FMDV, Applicants respectfully submit that such an amendment is not necessary. There is adequate written disclosure in the specification to support the genera of autocatalytic peptides, and no basis in law for requiring that the claims of the subject invention be limited to only those embodiments provided in the examples.

The term "autoproteolytic peptide" is defined in the specification at page 13, lines 11-14: "The autoproteolytic peptide is any amino acid sequence that can essentially independently cleave itself by breaking a peptide bond or covalent bond with its sequence in the presence of heterologous amino acid sequences at both its N- and C-terminal ends." Even absent this definition, the meaning of the term is self-explanatory. The specification goes on to state that "(o)ne of ordinary skill in the art is able to construct a fusion protein comprising an autoproteolytic peptide (DeFelipe, *et al.*, 2000; Gopinath, *et al.*, 2000; Kokuho, *et al.*, 1999; DeFilipe, *et al.*, 1999; Chaplin, *et al.*, 1999; Halpin, *et al.*, 1999; Donnelly, *et al.*, 1997; Mattion, *et al.*, 1996; Li, *et al.*, 1996; Ryan, *et al.*, 1994; Ryan, *et al.*, 1991)" (page 14, lines 19-23). The specification refers to numerous additional references containing information regarding autocatalytic polypeptides, such as Jackson and Hunter's 1989 review titled "Hordeivirus relationships and genome organization" (IDS reference #48); Palmenberg's 1990 paper on the proteolytic processing of picornaviral polyproteins (IDS reference #70); the 1977 publication by Palomar *et al.* titled "Base sequence homology in the RNAs of barley stripe mosaic virus" (IDS reference #71); and Petty *et al.*, EMBO Journal publication on "Identification of barley stripe mosaic virus genes involved in viral RNA replication and movement" (IDS reference #72). Even the 1997 Donnelly reference cited by the Examiner describes multiple autocatalytic polypeptides; the publication describes the cleavage activities of cardioviral as well as aphthoviral (e.g., FMDV) autocatalytic proteins, and notes that portions of the protein sequences are also conserved among TME and EMC viruses. Thus, as noted in the specification and supported by the numerous cited references, autoproteolytic peptides were known in the art at the time the subject invention was made.

As noted in *Hybri-tech Inc. v. Monoclonal Antibodies, Inc* (802F.2d 1367, 231 USPQ 81, Fed. Cir. 1986), a patent need not teach, and preferably omits, what is well known in the art. Autoproteolytic peptides were known in the art at the time of filing of the subject application, and are adequately described in the subject application. As such, Applicants submit that the claims are supported by the written description provided in the subject specification.

The Action further alleges that there is no structural description or functional requirement with respect to the "gamma b" and "beta b" viral proteins of claims 10, 13, 14 and 17-20. Claims 10 and 13 as amended are drawn to gamma-b and beta-b proteins from hordeiviruses, the a classification of proteins that is known in the art as well as disclosed in numerous publications cited in the specification. As such, the written description of the invention supports the claims with respect to the specified viral proteins.

Applicants submit that claims 1-6, 8-30 and 58 are drawn to subject matter that is described in the specification as required by 35 USC §112, first paragraph, and respectfully request that the rejection be withdrawn.

35 U.S.C. §103(a).

Claims 1-4 have been cancelled; thus, the applicability of the 103(a) rejection is not addressed by Applicants. Remaining claims 9-12, 15, 16, 19, 20 and 24-27 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Donnelly (J. General Virology (1997) 78:13-21) in view of Choi *et al.* (Plant Journal(2000) 23:547-555). Applicants traverse to the extent that the rejection applies to the pending claims.

With entry of this Amendment, claims 9-12, 15, 16, 19, 20 and 24-27 are dependent from, and include the limitations of, amended claim 5. Amended claim 5 is drawn to polynucleotides encoding a promoter operatively linked to a transcriptional unit, wherein the promoter comprises a promoter functional in a plant or plant cell; and wherein the transcription unit encodes a fusion protein comprising (1) a viral protein obtained from a plant single-stranded RNA virus, wherein the

plant single-stranded RNA virus is a hordeivirus; (2) a protein of interest, and (3) an autoproteolytic peptide comprising no more than 20 amino acids, wherein (3) is fused between (1) and (2).

A *prima facie* case of obviousness requires that the combination of the cited art, taken with the general knowledge in the field, must provide all of the elements of the claimed invention. Applicants submit that the cited art does not teach or describe all of the elements of amended claim 5. For example, the single-stranded plant RNA virus employed in Choi is wheat streak mosaic virus (WSMV), a member of the Potyviridae family of viruses. Choi does not teach or disclose viral proteins obtained from a hordeivirus (a member of the Togaviridae family of viruses). The Donnelly publication is directed toward aphthoviruses and cardioviruses (e.g., animal viruses, not plant viruses). Thus, the cited art does not teach or describe viral proteins obtained from a hordeivirus.

Since the cited art does not teach or describe all of the elements of the claimed invention, the first criterion for proving obviousness under §103(a) has not been met. Applicants respectfully request that the rejection be withdrawn.

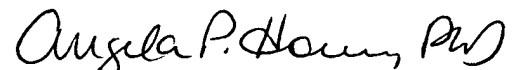
CONCLUSION

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the claims are deemed not to be in condition for allowance after consideration of this Response, a telephone interview with the Examiner is hereby requested. Please telephone the undersigned at (510) 337-7871 to schedule an interview.

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Respectfully submitted,


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Attachments:

- 1) A petition to extend the period of response for 1 months;
- 2) A transmittal sheet;
- 3) A fee transmittal sheet; and,
- 4) A receipt indication postcard.